Atty. Dkt. No. 025217-0122

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Barry Leonard REED et al.

Title:

DERMAL PENETRATION ENHANCERS AND DRUG DELIVERY SYSTEMS INVOLVING SAME

Appl. No.:

10/759,303

Filing Date:

01/20/2004

Examiner:

Konata George

Art Unit:

1616

## TERMINAL DISCLAIMER

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Petitioner, ACRUX DDS PTY LTD, having its principal place of business at 103-113 Stanley Street, West, Melbourne, Victoria 3003, Australia, represents that it is the owner of the entire right, title, and interest in and to U.S. Patent Application No. 10/7:59,303, filed 01/16/2004 (the "captioned application"), which is a continuation-in-part of U.S. Patent Application No. 09/910,780 filed 07/24/2001 (now U.S. Patent No. 6,818,226), which is a division of U.S. Patent Application No. 09/125,436 filed 12/18/1998 (now U.S. Patent No. 6,299,900), by virtue of an Assignment filed and recorded in the United States Patent and Trademark Office on September 9, 2004 at Reel/Frame 015115/0171, a copy of which is attached hereto as APPENDIX A.

Petitioner further represents that it is the owner of U.S. Patent No. 6,818,226 (issued from U.S. Patent Application No. 09/910,780); U.S. Patent Application No. 10/428,012; U.S. Patent Application No. 10/428,016; U.S. Patent Application No. 10/428,017, U.S. Patent Application No. 10/428,018 and U.S. Patent Application No.

Atty. Dkt. No. 025217-0122

10/428,019, by virtue of the Assignment filed and recorded in the United States Patent and Trademark Office on September 9, 2004 at Reel/Frame 015115/0171, a copy of which is attached hereto as APPENDIX A.

Petitioner further represents that it is the owner of U.S. Patent No. 6,299,900, which issued from U.S. Patent Application No. 09/125,436, filed 12/18/98, by virtue of an Assignment filed and recorded in the United States Patent and Trademark Office on September 10, 2004 at Reel/Frame 015116/0187, a copy of which is attached hereto as APPENDIX B.

Petitioner, ACRUX DDS PTY LTD, hereby disclaims the terminal part of the term of any patent granted on the captioned patent application (U.S. Patent Application No. 10/759,303) which would extend beyond the full statutory term, as shortened by any terminal disclaimer, of each of U.S. Patent No. 6,299,900; U.S. Patent No. 6,818,226; U.S. Patent Application No. 10/428,012; U.S. Patent Application No. 10/428,016; U.S. Patent Application No. 10/428,016; U.S. Patent Application No. 10/428,017; U.S. Patent Application No. 10/428,018 and U.S. Patent Application No. 10/428,019, and hereby agrees that any patent so granted on the captioned patent application shall be enforceable only for and during such period that the legal title to each of U.S. Patent No. 6,299,900; U.S. Patent No. 6,818,226; U.S. Patent Application No. 10/428,012; U.S. Patent Application No. 10/428,016; U.S. Patent Application No. 10/428,017; U.S. Patent Application No. 10/428,018 and U.S. Patent Application No. 10/428,019 shall be the same as the legal title to any patent granted on the captioned patent application, this agreement to run with any patent granted on the captioned patent application and to be binding upon the grantee, its successors or assigns.

In making the above disclaimer, Petitioner does not disclaim any terminal part of any patent granted on the captioned patent application prior to the full statutory term (as defined in 35 U.S.C. §§154-156 and 173) of U.S. Patent No. 6,299,900; U.S. Patent No. 6,818,226; U.S. Patent Application No. 10/428,012; U.S. Patent Application No. 10/428,016; U.S. Patent Application No. 10/428,017; U.S. Patent Application No. 10/428,018 anc/or U.S. Patent Application No. 10/428,019, in the event that any of U.S. Patent No. 6,299,900; U.S. Patent No. 6,818,226; U.S. Patent Application No. 10/428,012; U.S. Patent Application No.

Atty. Dkt. No. 025217-0122

10/428,016; U.S. Patent Application No. 10/428,017; U.S. Patent Application No. 10/428,018 and/or U.S. Patent Application No. 10/428,019 expires for failure to pay a maintenance fee, is held unenforceable or is found invalid in a final judgment by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR §1.321(a), has all claims canceled by a reexamination certificate or as a result of an interference proceeding, or is otherwise not deemed to provide the rights conveyed by 35 USC §154 prior to its full statutory term as defined in 35 USC §§154-156 and 173, except for the separation of legal title stated above.

Further, Petitioner does not disclaim any terminal part of a patent granted on the captioned patent application that would extend beyond the present term of any of U.S. Patent No. 6,299,900; U.S. Patent No. 6,818,226; U.S. Patent Application No. 10/428,012; U.S. Patent Application No. 10/428,016; U.S. Patent Application No. 10/428,017; U.S. Patent Application No. 10/428,018 and U.S. Patent Application No. 10/428,019, in the event that any such present term is extended by virtue of compliance with the conditions for term extension of any present or future patent term extension provision, including but not 1 mited to 35 U.S.C. §§155, 155A or 156, and does not waive Petitioner's right to extend the term of a patent granted on the captioned patent application to the extent provided by law.

The undersigned, being the Attorney of Record for the captioned patent application, and duly authorized to act on behalf of Petitioner, certifies that he has reviewed the Assignments attached as APPENDICES A and B, and to the best of his knowledge and belief, legal title to the captioned patent application and U.S. Patent No. 6,299,900; U.S. Patent No. 6,818,226; U.S. Patent Application No. 10/428,012; U.S. Patent Application No. 10/428,016; U.S. Patent Application No. 10/428,017; U.S. Patent Application No. 10/428,018 and U.S. Patent Application No. 10/428,019 rests with Petitioner, ACRUX DDS PTY LTD.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of

Atty. Dkt. No. 02521.7-0122

the United States Code, and that such willful false statements may jeopardize the validity of the captioned patent application or any patent issuing therefrom.

Respectfully submitted,

.

FOLEY & LARDNER LLP 3000 K Street, N.W. Suite 500

Washington, D.C. 20007-5109 Telephone: (202) 672-5404 Facsimile: (202) 672-5399 Stephen A. Bent Attorney for Applicant Registration No. 29,768